

THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of	:	Yu, et al.
Serial No.	:	10/574,392
Filing Date:	:	April 3, 2006
Examiner:	:	Not yet assigned
Group Art Unit:	:	Not yet assigned
Entitled:	:	MATERIALS AND METHODS TO BREAST CANCER CLASSIFICATION

Suite 2400
1601 Market Street
Philadelphia, PA 19103
(215) 563-4100 (telephone)
(215) 563-4044 (facsimile)
Our File No.0380-P04018US00

**INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. § 1.97**

In compliance with the duty of disclosure set forth in 37 C.F.R. § 1.56, Applicants are submitting herewith a Form PTO-1449. Because the filing date of this application is after June 30, 2003, only copies of the citations that are not U.S. Patents or U.S. Published Patent Applications are provided.

This Information Disclosure Statement is being filed more than three months after the filing date of the application. However, Applicants have not yet received an action on the merits of the application. Accordingly, Applicants believe that no fee is required pursuant to 37 C.F.R. § 1.97 (b) (3). In the event a fee is required, the Commissioner is authorized to charge the required fees to deposit account no. 04-1406.

Applicants respectfully request full and proper consideration of the listed

information during examination of the application, and that the listed information be printed on any patent that issues therefrom.

Respectfully submitted,

DANN, DORFMAN, HERRELL & SKILLMAN
A Professional Corporation
Attorneys for Applicant(s)

By 
Kathleen D. Rigaut, Ph.D., J.D.

PTO Registration No. 43,047
Telephone: (215) 563-4100
Facsimile: (215) 563-4044

Enclosures: Form PTO-1449

- Copy of foreign patent reference
- Copy of non-patent literature reference

INFORMATION DISCLOSURE STATEMENT

Complete if known

Application Number: 10574392

Filing Date: 2006-04-03

First Named Inventor: Kun Yu

Group Art Unit: Not yet assigned

Examiner Name: Not yet assigned

SHEET 1 OF 2

Attorney Docket Number: 0380-P04018US00

UNITED STATES PATENT DOCUMENTS

EXAMINER'S INITIALS	CITE NO.	PATENT NUMBER	ISSUE DATE MM-DD-YYYY	FIRST NAMED INVENTOR

FOREIGN PATENT DOCUMENTS

EXAMINER'S INITIALS	CITE NO.	DOCUMENT NUMBER	COUNTRY OR REGION	DATE OF PUBLICATION MM-DD-YYYY	FIRST NAMED INVENTOR OR APPLICANT
		PCT/GB03/00755	WO	08/28/2003	Tan, et al.
		PCT/US02/18947	WO	12/27/2002	Dai, et al.
		2004033210	Japan	05/02/2004	Ooi Chia Huey

OTHER CITATIONS - NON-PATENT DOCUMENTS

EXAMINER'S INITIALS	CITE NO.	Include name of the author (in Capital Letters), title of the article (when appropriate), title of the item(book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published
		AFFIMETRIX, INC., "Affimatrix GeneChip Human Genome U133 Array Set HG-U133A", GEO, 2002/3/11, whole document
		SATO, Norihiro, et al.; "Discovery of Novel Targets for Aberrant Methylation in Pancreatic Carcinoma Using High-Throughput Microarrays." Cancer Research, Vol. 63, No. 13, 1 July 2003. Pages 3735-3742.
		GRUVBERGER, Sofia, et al.; "Estrogen Receptor Status in Breast Cancer is Associated with Remarkably Distinct Gene Expression Patterns." Cancer Research, Vol. 61, No. 16. American Associate for Cancer Research: Baltimore, MD. Pages 5979-5984.
		WEST, Mike, et al.; "Predicting the Clinical Status of Human Breast Cancer by Using Gene Expression Profiles." Proceeding of the National Academy of Sciences of the United States of America, Vol. 98, No. 20. 25 September 2001. Pages 11462/11467.
		BERTUCCI, Francois, et al.; "Gene Expression Profiling of Primary Breast Carcinomas Using Arrays of Candidate Genes." Human Molecular Genetics, Vol. 9, No. 20. Oxford University Press: Surrey, Great Britain. 2000. Pages 2981-2991.

EXAMINER'S SIGNATURE	DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP §609. Draw a line through citation if citation not in conformance and reference not considered. Include a copy of this form with next communication to applicant.

INFORMATION DISCLOSURE STATEMENT

Complete if known

Application Number: 10574392

Filing Date: 2006-04-03

First Named Inventor: Kun Yu

Group Art Unit: Not yet assigned

Examiner Name: Not yet assigned

SHEET 2 OF 2

Attorney Docket Number: 0380-P04018US00

VAN'T VEER, Laura J., et al.; "Gene Expression Profiling Predicts Clinical Outcome of Breast Cancer." *Nature*, Vol. 415, No. 6871. Macmillan Journals, Ltd.: London, Great Britain. 31 January 2002. Pages 530-536.

VAN DE VIJVER, Marc J., et al.; "A Gene-Expression Signature as a Predictor of Survival in Breast Cancer." *The New England Journal of Medicine*, Vol. 347, No. 25. Massachusetts Medical Society: Boston, MA. Pages 1999-2009.

BERTUCCI, Francois, et al.; "Gene Expression Profiles of Poor-Prognosis Primary Breast Cancer Correlate with Survival." *Human Molecular Genetics*, Vol. 11, No. 8. Human Molecular Genetics: Surrey, Great Britain. 15 April 2002. Pages 863-872.

SORLIE, Therese, et al.; "Gene Expression Patterns of Breast Carcinomas Distinguish Tumor Subclasses with Clinical Implications." *Proceedings of the National Academy of Sciences of the United States*, Vol. 98, No. 19. National Academy of Science: Washington, D.C., USA. 11 September 2001. Pages 10869-10874.

YU, Kun, et al.; "A Molecular Signature of the Nottingham Prognostic Index in Breast Cancer." *Cancer Research*, Vol. 64, No. 9. American Association for Cancer Research: Baltimore, MD. 1 May 2004. Pages 2962-2968.

PEROU, Charles M., et al.; "Molecular Portraits of Human Breast Tumors." *Nature*, Vol. 406. MacMillan Magazines, Ltd.: London, Great Britain. 17 August 2000. Pages 747-752.

HEDENFALK, M.S., et al.; "Gene Expression Profiles in Hereditary Breast Cancer." *The New England Journal of Medicine*, Vol. 344, No. 8. Massachusetts Medical Society: Boston, MA. 22 February 2001. Pages 539-548.

KUN, Yu, et al.; "Classifying the estrogen receptor status of breast cancers by expression profiles reveals a poor prognosis subpopulation exhibiting high expression of the ERBB2 receptor." *Human Molecular Genetics*, Vol. 12, No. 24. Oxford University Press: Surrey, Great Britain. 15 December 2003. Pages 3245-3258.

SU, Andrew I., et al.; "Molecular Classification of Human Carcinomas by Use of Gene Expression Signatures." *Cancer Research*, Vol. 61. American Association for Cancer Research: Baltimore, MD. 15 October 2001. Pages 7388-7393.

PEROU, Charles M., et al.; "Distinctive Gene Expression Patterns in Human Mammary Epithelial Cells and Breast Cancers." *Proceedings of the National Academy of Sciences of USA*, Vol. 96, No. 16. National Academy of Science: Washington, D.C., USA. 3 August 1999. Pages 9212-9217.

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SIGNATURE

DATE
CONSIDERED

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	10574392
Filing Date	2006-04-03
First Named Inventor	Kun Yu
Art Unit	
Examiner Name	
Attorney Docket Number	0380-P04018US00

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

- ☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

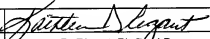
OR

- ☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

- ☐ See attached certification statement.
- ☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.
- ☒ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature		Date (YYYY-MM-DD)	2006-05-31
Name/Print	Kathleen D. Rigaut, Ph.D. J.D.	Registration Number	43,047

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

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3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.